

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/  
FENFLURAMINE/DEXFENFLURAMINE)  
PRODUCTS LIABILITY LITIGATION

MDL NO. 1203

THIS DOCUMENT RELATES TO:

SHEILA BROWN, et al.

CIVIL ACTION NO. 99-20593

v.

AMERICAN HOME PRODUCTS  
CORPORATION

2:16 MD 1203

THIS DOCUMENT RELATES TO:

CHRISTA McNUTT

v.

WYETH, INC.,  
f/k/a AMERICAN HOME PRODUCTS  
CORPORATION

CIVIL ACTION NO. 12-20010

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8991

Bartle, J.

January 16, 2013

Plaintiff Christa McNutt filed a lawsuit in the Superior Court of the State of Delaware in and for New Castle County against defendant Wyeth, Inc. ("Wyeth")<sup>1</sup>. The action was subsequently removed to the United States District Court for the District of Delaware and transferred to this court for pretrial proceedings as part of the Fen-Phen multi-district litigation,

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

MDL 1203. Ms. McNutt alleges that she suffers from primary pulmonary hypertension as a result of ingesting Wyeth's diet drugs known as Pondimin (fenfluramine) and Phentermine.

Pending before the court is Wyeth's motion to enjoin plaintiff from proceeding with her action on the ground that she is a class member in Brown v. American Home Products Corp., MDL No. 1203, and is barred by the Settlement Agreement approved by this court from litigating her pending claim.

This court approved the Settlement Agreement of this massive and complex diet drug class action in Pretrial Order ("PTO") No. 1415, In re Diet Drugs, No. 99-20593, 2000 WL 1222042 (E.D. Pa. Aug. 28, 2000). With certain exceptions, Ms. McNutt, as a class member, released all claims she had or may have against Wyeth for her use of diet drugs. The exception which is the focus of the pending motion allows class members to sue Wyeth in the tort system if they suffer from primary pulmonary hypertension ("PPH"), a fatal disease which can be caused by the use of Wyeth's diet drugs.

In order to be able to proceed with such a lawsuit, plaintiff must establish before this court as a threshold matter that she has evidence that satisfies the three-part definition of PPH as set forth in the Settlement Agreement. As explained in PTO No. 2623, "This court has the job of overseeing the settlement of this massive class action, particularly to insure that the Settlement Agreement, as approved by the court, is uniformly interpreted and properly enforced." Pursuant to that

role, this court must first make a determination as to whether there exists at least a genuine dispute of material fact that plaintiff suffers from PPH as defined in the Settlement Agreement. If plaintiff has not come forward with evidence to create such a genuine dispute, the court will enjoin her from proceeding with her lawsuit. If, on the other hand, plaintiff presents such evidence, the case may proceed to trial where it will be determined whether Wyeth is liable. See PTO No. 1415; PTO No. 3699.

The definition of PPH in the Settlement Agreement requires a plaintiff to come forward with evidence that excludes known causes of pulmonary arterial hypertension before he or she may proceed with a claim for PPH. The part of the exclusion that is in issue here reads:

"Primary Pulmonary Hypertension" ("PPH") is defined as either or both of the following:

- a. For a diagnosis based on examinations and clinical findings prior to death:

...

- (2) Medical records which demonstrate that the following conditions have been excluded by the following results:

- (a) Echocardiogram demonstrating no primary cardiac disease including, but not limited to, shunts, valvular disease (other than tricuspid or pulmonary valvular insufficiency as a result of PPH or trivial, clinically insignificant left-sided valvular regurgitation), and congenital heart disease (other than patent foramen ovale) [.]

§ 1.46(a)(2)(a) (emphasis added).

Wyeth argues that the court should issue an injunction because plaintiff's medical records show that she has a shunt in her heart. While conceding the records indicate a shunt, plaintiff counters that the shunt is through a patent foramen ovale ("PFO"). Plaintiff argues that the term "shunt" as used in the definition of Settlement Agreement does not include shunts associated with PFOs.

It is undisputed that an echocardiogram of plaintiff dated August 10, 2012 shows a "left-to-right" shunt. It is also undisputed that the shunt is through a PFO. As noted above, the echocardiogram must demonstrate "no primary cardiac disease, including but not limited to shunts ... and [to] congenital heart disease (other than patent foramen ovale)." In other words, while the echocardiogram must exclude primary cardiac disease including shunts and congenital heart disease, there is an exception for PFOs, that is, plaintiff's medical records do not have to exclude PFOs.

The question presented is whether the absence of "primary cardiac disease ... including shunts" that plaintiff must show through her medical records under § I.46(a)(2)(a) of the Settlement Agreement must encompass the absence of a shunt through a PFO. Put differently, we must decide whether the existence of a shunt through the PFO allows plaintiff to proceed with her lawsuit as a result of the carve-out of PFOs.

The definition of PPH, as reflected in the Settlement Agreement, was intended to set forth a medical consensus. See In

re Diet Drugs, No. 99-20593, 2000 WL 1222042 at \*30. We must, of course, adhere to the definition as written. But that does not mean we are prevented from referencing proper sources on the meaning of technical medical terms. As set forth in Williams v. Metzler, 132 F.3d 937, 947 (3d Cir 1997), a written agreement "is interpreted as a whole, and all writings that are part of the same transaction are interpreted together." Moreover, when dealing with a contract that uses technical, industry-specific terms, evidence as to the words' meaning is admissible. AstenJohnson, Inc. v. Columbia Cas. Co., 562 F.3d 213, 220 (3d Cir. 2009).

At the Fairness Hearing, there was extensive testimony from Robyn J. Barst, M.D., a leading expert on PPH, concerning the nature of the disease as well as written declarations from other physicians on the subject. There was no disagreement. Further, medical articles were not only introduced into evidence but actually cited in § 1.46 of the Settlement Agreement to explain and illuminate the definition of PPH. It is proper for the court to consider these sources in interpreting § 1.46 as well as the relevant findings and conclusions of my predecessor, Judge Louis C. Bechtle, in his thorough and well-reasoned Memorandum in support of PTO No. 1415 approving the Class Action Settlement.

A shunt is a condition wherein blood is diverted from its normal flow through the heart. Shunts typically result from a hole in the heart and disturb the equality of pulmonary blood

flow and systemic blood flow. A shunt is either left-to-right or right-to-left. Left-to-right shunts are usually caused by congenital heart disease, meaning cardiac defects present at birth, such as, most commonly, Atrial Septal Defects (ASDs) and Ventricular Septal Defects (VSDs). Left-to-right shunts are sometimes associated with pulmonary hypertension.

A patent foramen ovale is a common anatomical anomaly that results in a small opening between the left and right atria of the heart. PFOs can result in right-to-left, left-to-right, or "bidirectional" shunting. According to Dr. Barst, who, as mentioned previously, testified at the Fairness Hearing, PFOs, with or without shunts, are not associated with an increased risk of pulmonary hypertension. Dr. Barst further explained that Part 2(a) of the definition of PPH in the Settlement Agreement was intended to list the known causes of pulmonary arterial hypertension that were to be excluded in order for a Class Member to be able to proceed with a PPH claim against Wyeth in the tort system.

The crux of Wyeth's argument is that the plain language of Part 2(a) of the PPH definition in the Settlement Agreement forecloses Ms. McNutt's claim because it requires the absence of a shunt. Because Part 2(a) is measured by an objective standard, Wyeth contends it is irrelevant whether Ms. McNutt's shunt through the PFO caused her PPH.

In his Memorandum in support of PTO No. 1415, Judge Bechtle, referencing Dr. Barst's Fairness Hearing testimony,

describes PPH as a "diagnosis of exclusion" which requires that all "secondary" causes of pulmonary hypertension be excluded:

These include diseases known to be associated with pulmonary hypertension such as collagen vascular disease, congenital systemic to pulmonary shunts, portal hypertension, toxin-induced lung disease, significant obstructive sleep apnea, interstitial fibrosis (such as silicosis, asbestosis, or granulomatous disease), HIV infection and others.

Id. at 40 (emphasis added). Judge Bechtle's use of the description "congenital systemic to pulmonary shunts" is supported by the medical literature. Section I.46 of the Settlement Agreement cites the Executive Summary from the World Symposium on Primary Pulmonary Hypertension ("Evian Report"), which specifically notes that systemic to pulmonary shunts are a secondary cause of pulmonary hypertension and must be ruled out in order to reach a PPH diagnosis. The Evian Report nowhere mentions PFOs or shunts through PFOs as a secondary cause of pulmonary hypertension. In addition, Wyeth offered at the Fairness Hearing the declarations of two experts, Dr. Pravin Shah and Dr. Arthur Weyman, wherein they agreed on the secondary causes of pulmonary hypertension. Significantly, neither of them mentioned PFOs or shunts through PFOs.

Based on the medical literature, Judge Bechtle's use of the description "congenital systemic to pulmonary shunts," and the carve-out of PFOs from the PPH definitional exclusions, we conclude that "shunts," as written into § I.46(a)(2) of the Settlement Agreement, does not include shunts through a PFO and

means congenital systemic to pulmonary shunts. To interpret the Settlement Agreement to bar Ms. McNutt's claims on the basis of her PFO would contradict the medical consensus concerning PPH as incorporated into the Agreement and would distort the intent of the parties.

Accordingly, Ms. McNutt, as a threshold matter, has come forward with sufficient evidence to satisfy the definition of PPH in § I.46 of the Settlement Agreement. The motion of Wyeth to enjoin plaintiff from proceeding with her action will be denied.